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| 10/821,338      | 04/09/2004  | Christa Harris       | THR-6216            | 1230             |

7590 01/22/2007  
ALLEGIANCE CORPORATION  
ATTN: Kim Luna, KB-1A  
1430 Waukegan Rd  
McGaw Park, IL 60085-6787

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| EXAMINER |
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ROANE, AARON F

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| ART UNIT | PAPER NUMBER |
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3739

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 01/22/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                 |               |  |
|------------------------------|-----------------|---------------|--|
| <b>Office Action Summary</b> | Application No. | Applicant(s)  |  |
|                              | 10/821,338      | HARRIS ET AL. |  |
|                              | Examiner        | Art Unit      |  |
|                              | Aaron Roane     | 3739          |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of specie 1 in the reply filed on 10/30/2006 is acknowledged. Claims 13 and 16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected specie, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10/30/2006.

Applicant's election with traverse of specie 1 in the reply filed on 10/30/2006 is acknowledged. The traversal is on the ground(s) that

*"The office action does not claim that there are separate inventions classified in different classifications, but rather that the claims are directed to species of a genus. It should not be a burden on the Examiner to search for all of species in this case, rather than one, and the Examiner is respectfully requested to withdraw the species restriction requirement.*

*There are only two species, and if generic or linking claims (claim 1-11 and 14) are allowed, the restriction requirement must be withdrawn, and the claims examined. M.P.E.P. 809 at 800-48 (8th ed. Rev. 2). Accordingly, it may be less burdensome on the Examiner to examine multiple species at once, rather than repeating the process,"*

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see last line of page 1 through page 2, line 8. This is not found persuasive because 1) the species have different fields of search, 2) the examiner disagrees with Applicant and believes the search to be burdensome and finally, 3) none of the generic claims are allowable.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitahara et al.

(USPN 5,261,241) in view of Maro et al. (USPN 5,491,018) and in further view of Helmeg (USPN 6,648,909 B2).

Regarding claims 1 and 3-7, Kitahara et al. disclose a topically applied thermal device (13) comprising a flexible plastic containment (10, 12 and 14) and a single activatable thermochemical liquid composition (e.g., B, the water and 8-hydrate of strontium hydroxide mixture shown in figure 2) encased therein, said flexible plastic containment comprising a multilayer film (10, 12 and 14) comprising: an outer polymeric barrier layer

(12) comprising a coating (10), and an inner polymeric sealant layer (14). Kitahara et al. further disclose that the outer polymeric layer is comprised a layer of polyester (12) coated with a layer of aluminum (12) in order to provide the device with a liquid impervious, leak proof layer see col. 5, lines 29-61, col. 10 and figure 2. Kitahara et al. also disclose the flexible plastic containment (10, 12 and 14) defines a single interior compartment (see single interior compartment shown in figure 2). Kitahara et al. fail to disclose that the coating is either aluminum oxide or silicon oxide coating. Kitahara et al. also fail to disclose that the inner polymeric sealant layer comprises a blend of low density polyethylene (LDPE) and ethylvinyl acetate (EVA). Maro et al. disclose a laminated packing material and teach the coating of polyester with a silicon oxide layer in order to provide the device with a liquid impervious, leak proof layer, see col. 1-12, particularly col. 1, lines 9-23 and col. 3, lines 31-37. Helmeg discloses a hot/cold pack and teaches the use of making a inner layer, seal and/or bag from LDPE in order to provide a burstable/rupturable barrier to the device, see col. 1-6 and figures 1-9. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Kitahara et al., as taught by Maro et al., to coat the polyester layer with a silicon oxide layer in order to provide the device with a liquid impervious, leak proof layer, and as further taught by Helmeg, to make the inner layer, seal and/or bag from LDPE in order to provide a burstable/rupturable barrier to the device. Finally, at the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to use an inner polymeric sealant layer comprised of low density polyethylene (LDPE) because Applicant has not disclosed that

an inner polymeric sealant layer comprising a blend of low density polyethylene (LDPE) and ethylvinyl acetate (EVA) provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with only the LDPE because it also provides the burstable/rupturable capabilities.

Regarding claim 2, Kitahara et al. further disclose a device comprising an adhesive layer laminating together said outer polymeric barrier layer and said inner polymeric sealant layer, see col. 6.

Regarding claim 8, Kitahara et al. disclose the claimed invention, see col. 1-16.

Regarding claims 9 and 10, Kitahara et al. disclose the claimed invention, see col. 1-16.

Claims 1, 6, 11, 12, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (USPN 6,283,116) in view of Maro et al. (USPN 5,491,018) and in further view of Helmeg (USPN 6,648,909 B2).

Regarding claim 1, 6, 11, 12, 14 and 15, Yang discloses a topically-applied thermal device comprising a flexible plastic containment (11) defining a single interior compartment and a single activatable thermochemical liquid composition 13) encased therein, said flexible plastic containment comprising polymeric sealant layer (see col. 2,

lines 3-7), and a flexible physical activator element, in the form of a flexible perforated disc (15) within the single interior compartment operative to initiate an exothermic reaction when flexed, see col. 2 and 3 and figures 2-4. Yang fails to disclose that the coating is an oxide coating. Yang also fails to disclose that the inner polymeric sealant layer comprises a blend of low density polyethylene (LDPE) and ethylvinyl acetate (EVA). Maro et al. disclose a laminated packing material and teach the coating of polyester with a silicon oxide layer in order to provide the device with a liquid impervious, leak proof layer, see col. 1-12, particularly col. 1, lines 9-23 and col. 3, lines 31-37. Helmeg discloses a hot/cold pack and teaches the use of making a inner layer, seal and/or bag from LDPE in order to provide a burstable/rupturable barrier to the device, see col. 1-6 and figures 1-9. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Yang, as taught by Maro et al., to coat the polyester layer with a silicon oxide layer in order to provide the device with a liquid impervious, leak proof layer which in turn prevents liquid/solution evaporation from the plastic containment and prolongs the life of the device, and as further taught by Helmeg, to make the inner layer, seal and/or bag from LDPE in order to provide a burstable/rupturable barrier to the device. Finally, at the time of the invention, it would have been an obvious matter of design choice to one of ordinary skill in the art to use an inner polymeric sealant layer comprised of low density polyethylene (LDPE) because Applicant has not disclosed that an inner polymeric sealant layer comprising a blend of low density polyethylene (LDPE) and ethylvinyl acetate (EVA) provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary

skill in the art, furthermore, would have expected Applicant's invention to perform equally well with only the LDPE because it also provides the burstable/rupturable capabilities.

### *Response to Arguments*

Applicant's arguments filed 7/21/2006 have been fully considered but they are not persuasive. Applicant asserts that "Kitahara et al. and Maro et al. address very different problems" and therefore Ruiz lends no support to the examiner's conclusions, see page 5, lines 2-7. The examiner is not arguing the fact that Kitahara et al. and Maro et al. differ in they stated objects. However, Kitahara et al. disclose a device comprising a polymeric enclosure containing a liquid. This liquid and the preservation of this liquid in the enclosure is necessary desired functioning of the thermal device. Maro et al. disclose a flexible laminated polymeric food packaging material that is capable of preventing/reducing liquid loss/evaporation. The combined teachings of the references would suggest to one of ordinary skill in the art that the flexible laminated polymeric coating of Maro et al. would improve the shelf-life of the liquid containment thermal device of Kitahara et al. by preventing/reducing liquid loss/evaporation. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re



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Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F. 2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969). It should be pointed out, the combination to combine Yang and Maro et al. (and Helmeg) would be defended in a similar manner.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

**This action is made FINAL.**

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Roane  
January 9, 2007

*A.R.*

*Roy D. Gibson*  
ROY D. GIBSON  
PRIMARY EXAMINER